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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,343	08/01/2003	Peter A. Burke	ST8635US	3733
22203	7590	06/28/2005	EXAMINER	
KUSNER & JAFFE HIGHLAND PLACE SUITE 310 6151 WILSON MILLS ROAD HIGHLAND HEIGHTS, OH 44143				MCKANE, ELIZABETH L
ART UNIT		PAPER NUMBER		
		1744		

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/633,343	BURKE ET AL.
	Examiner Leigh McKane	Art Unit 1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 April 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3-9 and 11-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 23-25 is/are allowed.
- 6) Claim(s) 1,3-9 and 11-22 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 103

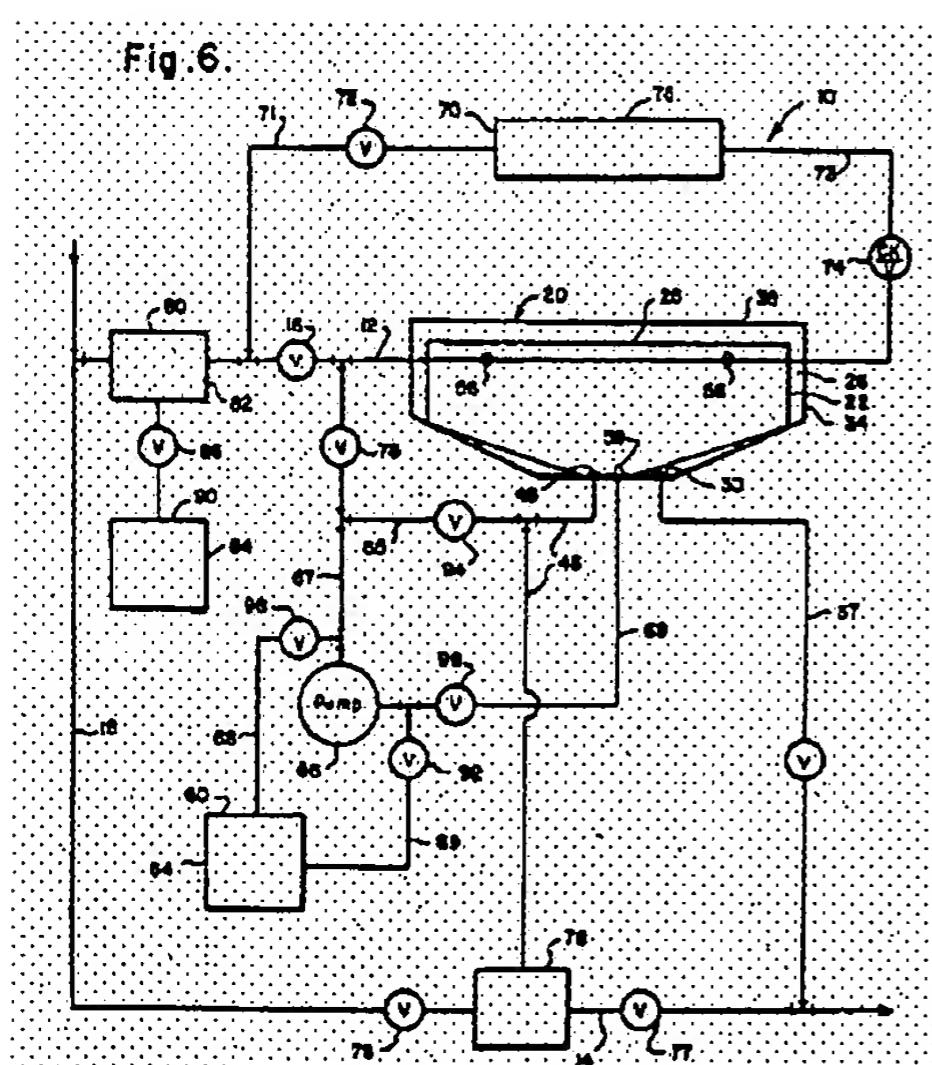
1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 1, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sundheimer (U.S. Patent No. 4,617,065) in view of Pall et al (U.S. Patent No. 4,431,545).

Sundheimer teaches an endoscope reprocessor 10 having a circulation system 67,69, 48, 71,73, a chamber 22, and a water filtration system 75. The fluid feed line 71 connects to

both the filtration system 75 and a bypass line 12, wherein fluid can bypass the filter system 75. Although the last paragraph of the claim is considered to be an intended use recitation, when valve 16 of Sundheimer is closed, all water entering the reprocessor 10 will first pass through the feed line and the filtration system. See col.4, lines 44-

Fig. 6.

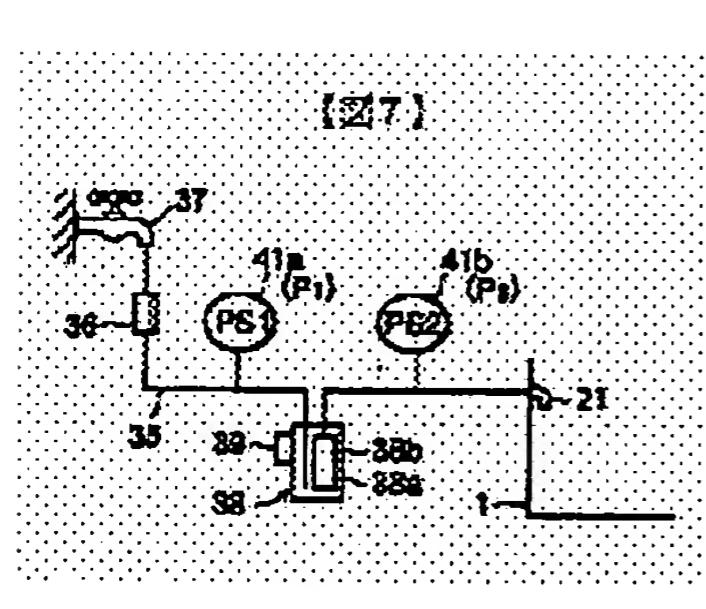


46. Sundheimer discloses that the water filtration system 75 "includes a series of filters" and "can be any commercially available filters which remove medically undesirable microbes" (col.4, lines 45-49), but does not teach that the filtration system includes first and second filters wherein the second filter is downstream of the first filter and has the capacity to filter particles smaller than the first filter.

Pall et al teaches a filter system comprised of a first filter having an absolute pore rating of about 0.1 to about 1.0 μm and a second downstream filter having an absolute pore rating of about 0.02 to about 0.1 μm . The filter system is effective in removing bacteria and endotoxins and can be employed in the form of a single filter cartridge or two separate filter cartridges used in a series arrangement. See Abstract; col.11, lines 42-47; col.16, line 64 to col.15, line 6. As the filter system of Pall is effective in providing medical grade water, it would have been obvious to use as the filter system of 75.

4. Claims 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sundheimer and Pall et al as applied to claim 1 above, and further in view of Nakanishi et al (JP 11-128158, hereinafter "Nakanishi et al – JP").

While Sundheimer does teach a means (valves 72,74) by which to isolate the filters 75 from the circulation system, neither Sundheimer nor the combination with Pall et al disclose a means to isolate the filters from each other or a means by which to determine filter integrity. Nakanishi et al – JP, however teaches an endoscope reprocessor including a means for determining filter integrity by using upstream \mathbf{P}_1 and downstream \mathbf{P}_2 measurements of pressure. See Figure 7. It



The diagram illustrates a flow circuit for an endoscope reprocessor. A main horizontal line represents the flow path. On the left side, there is a vertical branch with a valve labeled 37. From this branch, a line goes down to a valve labeled 36, which then connects to a circular component labeled PS1. Another line from this component goes up to a valve labeled 35. From valve 35, a line goes down to a valve labeled 38, which then connects to a circular component labeled PS2. From PS2, a line goes up to a valve labeled 39. From valve 39, a line goes down to a valve labeled 38a. From valve 38a, a line goes down to a valve labeled 38b. From valve 38b, a line goes down to a valve labeled 21. Above the main horizontal line, there is a bracket labeled {27} spanning the area between valves 37 and 21. The entire assembly is contained within a dotted rectangular border.

would have been obvious to one of ordinary skill in the art to use the filter integrity determining means of Nakanishi et al – JP in the apparatus of Sundheimer with Pall et al, because Nakanishi et al – JP discloses that the determining means can notify the user when the filter needs to be replaced. This is essential as filters become clogged and fail to function properly. The apparatus of Nakanishi et al – JP discloses using only a single filter **38b** for the reprocessor and thus is silent with respect to isolating two filters from each other. However, when applying the system of Nakanishi – JP to the combination of Sundheimer with Pall et al, one would have found it obvious to test the filters separately and doing so would have required that they be isolated.

5. Claims 9, 11-13 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sundheimer in view of Pall et al and Nakanishi et al (EP 0945140, hereinafter “Nakanishi et al – EP).

With respect to claims 9, 18-20, Sundheimer teaches an endoscope reprocessor **10** having a circulation system **67,69,48**, a sterilizing chamber **22**, a means for generating a liquid sterilant **82**, a means **66** for circulating sterilant through the circulation system, and a water filtration system **75** located in a fluid feed line **71**. The fluid feed line **71** connects to both the filtration system **75** and a bypass line **12**, wherein fluid can bypass the filter system **75**. When valve **16** of Sundheimer is closed, all water entering the reprocessor **10** will first pass through the feed line and the filtration system. See col.4, lines 44-46. The method of using the reprocessor includes the steps of filling the chamber with water which has passed through filters **75** (col.4, lines 14-15 and lines 44-47; col.7, lines 13-15), generating a liquid sterilant using filtered water (col.4, lines 37-49), and directing liquid sterilant through the feedline/filters (col.4, lines 59-63). Sundheimer discloses that the water filtration system **75** “includes a series of filters” and “can be any

commercially available filters which remove medically undesirable microbes" (col.4, lines 45-49), but does not teach that the filtration system includes first and second filters wherein the second filter is downstream of the first filter and has the capacity to filter particles smaller than the first filter. Sundheimer further fails to teach generating the liquid sterilant from dry chemical reagents.

Pall et al teaches a filter system comprised of a first filter having an absolute pore rating of about 0.1 to about 1.0 μm and a second downstream filter having an absolute pore rating of about 0.02 to about 0.1 μm . The filter system is effective in removing bacteria and endotoxins and can be employed in the form of a single filter cartridge or two separate filter cartridges used in a series arrangement. See Abstract; col.11, lines 42-47; col.16, line 64 to col.15, line 6. As the filter system of Pall is effective in providing medical grade water, it would have been obvious to use as the filter system of 75.

Nakanishi et al – EP discloses an endoscope reprocessor having a means for generating a liquid sterilant by admixture of a concentrated chemical with water wherein the chemical may take the form of a liquid, powder, or solid. See page 5, paragraphs [0032], [0033], and [0041]. As Nakanishi et al – EP evidences the use of dry, as well as wet, chemical reagents, one of ordinary skill in the art would have found it obvious to substitute one for the other in the system of Sundheimer.

With respect to the last paragraph of claim 9, beginning with "said sterilizer having a water fill phase...," this paragraph is considered to be a recitation of the intended use of the device and does not appear to limit the structure of the device.

As to claims 12, 13, and 21, Sundheimer teaches that UV radiation instead of filters may be used to sterilize the infeed water. See col. 7, lines 8-9. It is not deemed inventive to use both the filters and UV radiation disclosed by Sundheimer to sterilize the water, as using both would amount to a means of sterility assurance and would have been found obvious by the skilled practitioner. With respect to the location of the UV device, Nakanishi et al – EP evidences use of a water sterilization device (filter 7) which is located outside of the fluid circulation system. It would have been obvious to one of ordinary skill in the art to determine the most appropriate infeed location for the UV device to avoid overcooling of and chemical buildup on the lamp.

6. Claims 14-17 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sundheimer, Pall et al, and Nakanishi et al -- EP as applied to claims 9 and 19 above, and further in view of Nakanishi et al – JP.

While Sundheimer does teach a means (valves 72,74) by which to isolate the filters 75 from the circulation system, neither Sundheimer nor the combination *supra* disclose a means to isolate the filters from each other or a means by which to determine filter integrity. Nakanishi et al – JP, however teaches an endoscope reprocessor including a means for determining filter integrity by using upstream P_1 and downstream P_2 measurements of pressure. See Figure 7. It would have been obvious to one of ordinary skill in the art to use the filter integrity determining means of Nakanishi et al – JP in the apparatus of the combination, because Nakanishi et al – JP discloses that the determining means can notify the user when the filter needs to be replaced. This is essential as filters become clogged and fail to function properly. The apparatus of Nakanishi et al – JP discloses using only a single filter 38b for the reprocessor and thus is silent

with respect to isolating two filters from each other. However, when applying the system of Nakanishi – JP to the combination *supra*, one would have found it obvious to test the filters separately and doing so would have required that they be isolated.

Allowable Subject Matter

7. Claims 23-25 are allowed.
8. The following is an examiner's statement of reasons for allowance: The closest prior art, Nakanishi et al – JP, teaches the use of pressure measurements to test a single filter in an endoscope reprocessor. However, Nakanishi et al – JP fails to teach or suggest the specific method of filter integrity testing as set forth in claim 23 specifically.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Arguments

9. Applicant's arguments filed 11 April 2005 have been fully considered but they are not persuasive.
10. As set forth in the rejections *supra*, Sundheimer in combination with the secondary references Pall et al and Nakanishi et al, teaches the claimed invention. The amendments to the claims submitted 11 April 2005 fail to overcome the rejection as Sundheimer does indeed teach a

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fluid feed line **71** in connection with a filtration system and a bypass line **12**. When valve **16** is closed, all fluid will flow through the filtration system before entering the reprocessor.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Wednesday (6:30 am-4:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leigh McKane
Leigh McKane
Primary Examiner
Art Unit 1744

elm
27 June 2005